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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/676,380 | 09/29/2000 | Andre T. Baron | 99-057 | 1919 |

7590

05/07/2002

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EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/07/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/676,380

Applicant(s)

BARON ET AL.

Examiner

Janet L Andres

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III in Paper No. 13 is acknowledged. The traversal is on the ground(s) that separate examination and search are not required. Applicant further states that Groups I and III are in the same class. This is not found persuasive because the Groups are classified in separate subclasses and thus separate searches are required.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-23 are pending in this application. Claims 1-8 are withdrawn from consideration as drawn to a non-elected invention.

Specification

The disclosure is objected to because of the following informalities: There are blank spaces on page 42. In addition, the criteria for menopause status set forth on p. 53, lines 11-14, appear to be incomplete.

Appropriate correction is required.

The use of trademarks has been noted throughout this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1646

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 12-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of soluble ErbB1 in a sample lacking the p170 form of ErbB1, does not reasonably provide enablement for detection in all biological samples. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The antibodies used by Applicant interact with the extracellular domain of ErbB1. They thus interact with cell-surface EGF receptor and have been used by Applicant (pp. 46-49) and by others in the art (e.g. Graus-Porta et al., EMBO J., 1997, vol. 16, pp. 1647-1655 and Olayioye et al., J. Biol. Chem., 1999, vol. 274, pp.17209-17218) to detect the p170 form. While Applicant's claims are drawn to detection of the soluble form, there is no method step that would insure that this form was what was detected if other forms were present. One of skill in the art would not therefore predict that the claimed method could be used to detect soluble ErbB1 as opposed to the cell surface forms. Thus, without further direction, one of skill in the art would not be able to use the invention as broadly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harvey et al., U.S. patent 6,674,753, 1997, Partanen et al. (J. Occup. Med., 1994, vol. 36, pp 1324-1328) or Witters et al. (Clin. Cancer Res., 1995, vol. 1, pp.551-557) in view of Graus-Porta et al. or Olayioye et al., cited above, and further in view of WO 94/11734 (Johansen et al., 1994). Partanen et al. and Witters et al., cited by Applicant on p. 3 of the specification, teach the detection of soluble forms of the EGF receptor in serum (Partanen et al.) or urine (Witters et al.) of patients with cancer. The '753 patent teaches detection in serum, blood, and plasma. None of these references teaches the antibodies used by Applicant, or the assay technique used by Applicant. Both Graus-Porta et al and Olayioye et al. teach the antibodies used by Applicant for detection of the EGF receptor; as stated above, these antibodies are against the extracellular region and thus detect both soluble and cell-surface forms of the receptor. None of these

Art Unit: 1646

references teach the assay method used by Applicant. Johansen et al. teaches an assay method in which one detecting reagent is immobilized using paramagnetic particles, the second is labeled with biotin, and the complex is detected with acridinium bound to streptavidin. Johansen et al. does not teach direct labelling with acridinium ; however, such a modification would be *prima facie* obvious to one of ordinary skill in the antibody art as a substitute for binding of the avidin-linked complex to the biotinylated molecule. Johansen et al. also does not teach detection of soluble EGF receptor. However, it would have been obvious to one of ordinary skill in the art to modify the method of Johansen et al. to detect such receptors using the antibodies taught by Graus-Porta et al. and Olayioye et al. One of ordinary skill would have been motivated to do so because Partanen et al., Witters et al., and the '753 patent all teach that such detection is useful, Graus-Porta et al. and Olayioye et al. teach antibodies that detect the extracellular region of the receptor, and Johansen et al. teaches an improved method of detection using labeled antibodies. Thus one of ordinary skill would know that the detection of soluble EGF receptors was useful, that mABs R.1 and 528 could be used to detect soluble EGF receptors, and that the assay of Johansen et al. would be expected to be useful for such detection.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

Art Unit: 1646

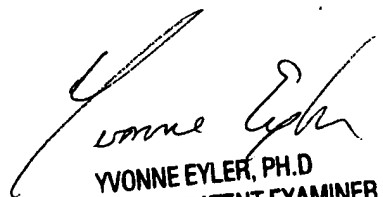
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
April 30, 2002


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
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